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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,745	08/22/2000	Anders Edlund	1103326-0633	2661

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EXAMINER
LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
1647	8

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/622,745	Applicant(s) EDLUND ET AL.	
	Examiner Robert Landsman	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-21 and 28-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Formal Matters

A. Preliminary Amendment A, filed 12/28/01, has been entered into the record.

B. The Information Disclosure Statement, filed 1/25/02, has been entered into the record.

C. Claims 1-31 are pending and were subject to restriction. Applicants elected Group III, claims 22-27, with traverse, stating that all of the Groups should be combined since, according to 37 CFR 1.475(a) and PCT Rule 13.2, there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features. However, this application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated below:

The invention of Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of claims 1-4 of Group I are a nucleic acid molecule constituting a human GABAB receptor 1 promotor P1a or 1b, or a functionally equivalent modified form thereof, an active fragment thereof. These claims are anticipated by Mu et al. (Brain Res. Mol Brain Res 67:137-147, 1999). Page 5 of the specification teaches that a "functionally equivalent modified form" of a promoter is a nucleic acid modified from the original sequence that can bind transcription factors. "Active fragments" are nucleic acid molecules that can bind transcription factors. Therefore, Group I lacks novelty or inventive step and does not make a contribution over the prior art. Therefore, Group III, claims 22-27 will be examined.

2. Objections

A. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81. No new matter may be introduced in the required drawing.

3. Claim Rejections - 35 USC § 112, first paragraph – enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 22-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims recite a method of screening compounds by transfecting cells with the GABA promoters of SEQ ID NO:1 and 2 as well as with "**functionally equivalent modified forms**," or "**active fragments**" of all $GABA_B$ receptor 1 P1a and P1b promoters, or with those which "**hybridize**" under stringent conditions to those of SEQ ID NO:1 or 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

First, claims 22-24, 26 and 27 recite a method of screening compounds for modulation of GABA receptors. However, the claim recites nothing about the transfected host cell having, or being transfected with, a $GABA_B$ receptor. Even though claim 25 does recite that the cell endogenously expresses a $GABA_B$ receptor, none of the claims recite how the introduced GABA promoters of the claims would integrate in the genome in a position such that it is able to affect the expression of the GABA receptors. Furthermore, even if Applicants were able to amend the claims to address this issue, the scope of the claims is excessive.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to claiming a method of screening compounds by transfecting cells with "functionally equivalent modified forms," or "active fragments" of all $GABA_B$ receptor 1 P1a and P1b promoters, or those which "hybridize" under stringent conditions to SEQ ID NO:1 and 2. These methods would involve promoters encoded for by nucleic acid molecules which comprise one or more nucleic acid substitutions, deletions, insertions and/or additions to the promoter sequences encoded for by SEQ ID NO:1 and 2. On page 5 of the specification, Applicants define a "functionally equivalent modified form" of a promoter is a nucleic acid modified from the

original sequence that can bind transcription factors and they define "active fragments" as nucleic acid molecules that can bind transcription factors.

Applicants provide no guidance or working examples of promoter nucleic acid sequences which differ from SEQ ID NO:1 and 2, nor do they provide any guidance of how to make a functional $GABA_B$ receptor 1 promoter P1a or P1b other than those of SEQ ID NO:1 or 2. Applicants provide no information as to what critical residues are necessary to maintain the "function" or "activity" of the claimed modified GABA promoters. According to the definition in the specification of these modified forms, every nucleic acid of the promoter can be altered and it is not predictable to the artisan what residues of the promoter sequences can be altered in order to maintain a functional promoter, or active fragment thereof.

In summary, the breadth of the claims is excessive with regard to Applicants claiming a method of screening compounds by transfecting cells with "functionally equivalent modified forms," or "active fragments" of all $GABA_B$ receptor 1 P1a and P1b promoters, or those which "hybridize" under stringent conditions to SEQ ID NO: 1 and 2. Applicants provide no guidance or working examples of promoter nucleic acid sequences which differ from SEQ ID NO:1 and 2, nor do they provide any guidance of how to make a functional $GABA_B$ receptor 1 promoter P1a or P1b other than those of SEQ ID NO:1 or 2, nor is it predictable to the artisan what residues of the promoter sequences can be altered in order to maintain a functional promoter, or active fragment thereof. For these reasons, the Examiner holds that undue experimentation is necessary to practice the invention as claimed.

4. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 22-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. Method of screening compounds by transfecting cells with "**functionally equivalent modified forms**," or "**active fragments**" of all $GABA_B$ receptor 1 P1a and P1b promoters, or those which "**hybridize**" under stringent conditions to SEQ ID NO:1 and 2. These methods would involve promoters encoded for by nucleic acid molecules which comprise one or more nucleic acid substitutions, deletions, insertions and/or additions to the promoter sequences encoded for by SEQ ID NO:1 and 2. The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is

permitted. The specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the nucleic acid or protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO:1 and 2, or molecules which hybridize to these polynucleotides (which could be at least thousands of molecules) alone are insufficient to describe the genus.

The specification provides a written description of only a small number of these nucleic acid constructs (SEQ ID NO:1 and 2). No other species are described, or structurally contemplated, within the instant specification. Therefore, one skilled in the art cannot reasonably visualize or predict critical nucleic acid residues which would structurally characterize the genus of nucleic acids of promoters in the claimed methods, because it is unknown and not described what structurally constitutes any different nucleic acids of these promoters, or nucleic acids of these promoters from any different species, which are further not described, or any different nucleic acid sequence that hybridizes to that depicted as SEQ ID NO:1 or 2; thereby not meeting the written description requirement under 35 USC 112, first paragraph. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

5. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is vague and indefinite since the claim recites "stringent conditions." It is not known what these conditions are. Nucleic acid molecules which hybridize under conditions of "low" stringency would not necessarily hybridize under conditions of "high" stringency. Furthermore, not all conditions of "high" or "low" stringency, for example, are the same. Therefore, it is required that Applicants amend the claims to recite the exact hybridization conditions without using indefinite phrases such as "*for example*" **without adding new matter**.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
March 11, 2002

GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
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